

### **REMARKS**

This amendment is filed in response to the Non-Final Office Action dated May 28, 2008. Claims 1-5, 13-18, 20, 21 and 26-56 had been presented. Claims 1, 26, 32, 38, 45 and 50 have been amended. Claims 1-5, 13-18, 20, 21, 26-56 are pending. Applicant respectfully requests reconsideration.

#### **Interview of September 15, 2008**

Applicant thanks Examiner Gettman for the courtesies extended during the interview of September 15, 2008. During this interview, the participants discussed claims 1, 26, 32, 38, 45 and 50 with respect to Horzewski et al. (U.S. Patent No. 5,318,588 (hereinafter "Horzewski")) and Leschinski (U.S. Patent No. 6,346,092). The above-noted amendments were discussed as overcoming the applied art.

#### **35 U.S.C. § 102:**

Claims 38, 39 and 42 are rejected under 35 U.S.C. § 102(b) as being anticipated by Horzewski. Horzewski fails to disclose each feature recited in claims 38, 39 and 42.

The combination of features in claim 38 provides a novel conduit that is not disclosed or even suggested by Horzewski. For example, claim 38 recites, *inter alia*, that the conduit has at least one layer with first and second types of sections varying in a circumferential direction, the circumferential direction lying in a plane perpendicular to a longitudinal direction of the conduit, wherein the elasticity of one of the sections is greater than the elasticity of another one of the sections. At least this feature is not disclosed by Horzewski.

Horzewski discloses a composite tube for an intravascular medical device, shown in Figures 1A-1D. Figure 1B represents a tubular element 14 surrounding an inner element 11. Figure 1D provides another arrangement including an outer tubular member 14 surrounding an inner member 10. Horzewski describes that element 11 of Figure 1B may be a relatively inelastic yet flexible

tubular element, while element 14 may be a relatively elastic tubular element (see column 7, lines 50-65 of Horzewski). The respective elements 11 and 14 of Horzewski would be understood by a skilled artisan as being homogeneous. That is, elements 11 and 14 respectively have uniform elasticity material properties throughout.

As one skilled in the art will appreciate, a “circumferential direction” is a direction that follows the circumference of an element. For example, the circumferential direction of element 11 in Figure 1B of Horzewski is the direction following the circumference of element 11 in either a clockwise or counterclockwise direction with respect to the illustrated view. The elasticity of element 11 is the same along its entire circumference. Similarly, the elasticity of element 14 is the same along its circumference.

In contradistinction, claim 38 describes that the at least one layer has first and second types of sections varying in a circumferential direction, the circumferential direction lying in a plane perpendicular to a longitudinal direction of the conduit. At least this feature is not disclosed by Horzewski. If one were to trace the circumference of either element 11 or 14 in Horzewski, it would be observed that the elasticity of element 14 does not change along a circumference that lies in a plane perpendicular to a longitudinal direction of the conduit.

Accordingly, Horzewski fails to disclose each feature recited in claim 38, such that the rejection thereof should be withdrawn. The rejection of claims 39 and 42 should likewise be withdrawn at least by virtue of these claims respectively depending from claim 38.

**35 U.S.C. § 103:**

Claims 1-5, 13-16, 20, 21, 32, 37 and 45-52 are rejected under 35 U.S.C. § 102(b) <sup>1</sup> as being anticipated by Horzewski in view of Leschinski (U.S. Patent No. 6,346,092).

As a preliminary matter, claims 20 and 21 depend from independent claim 38. Claim 38 has not been rejected in view of Horzewski and Leschinski. However, as noted above, Horzewski does

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<sup>1</sup> It is assumed the Examiner intended to state “35 U.S.C. § 103 (a) as being obvious...”

not disclose or even teach the features of claim 38. Leschinski fails to make up for the deficient teachings of Horzewski, such that claims 38, 20 and 21 are patentable over Horzewski and Leschinski even in view of such a rejection.

Claim 1 recites that the circumference of the inner layer is discontinuous and non-overlapping. Claim 32 contains a similar recitation.

Horzewski discloses that “the opposing surfaces of the inner tubular elements, contained within shaft sections 5 and 6, are *superimposed* upon one another,” teaching to overlap surfaces of element 11 (see Figure 1B and column 8, lines 41-43 of Horzewski). Horzewski goes on to emphasize that “this configuration enables the tubular elements to expand radially within the distal aspect of the catheter and yet remain *circumferentially intact* thus *precluding the inadvertent escape* of a device contained therein through the confines of a *slit 13*” (see column 8, lines 45-48). In other words, this teaching in Horzewski requires element 11 to be overlapping to provide proper expansion while keeping the delivered device from escaping through the slit 13.

The grounds of rejection acknowledge that Horzewski does not disclose a conduit having an inner layer that is non-overlapping. Thus, Leschinski is applied for teaching an intra-aortic balloon catheter system having an expandable distal end. This distal end can be seen in Figure 3 of Leschinski and includes scores 80 forming a scored end 70. The scored end allows for the sheath 20 to flare open and permits passage of balloon membrane 40. The scored end 70 in the flared open position is shown in Figure 3B of Leschinski.

In particular, Leschinski teaches:

“scored end 70 acts as a funnel preventing the unfurled balloon membrane from becoming snagged on the distal end of the insertion sheath 20. Upon withdrawal of the insertion sheath 20 from the patient the vasculature of the patient forces the scores 80 back to their original configuration, as illustrated in FIG. 3A, allowing for a smooth removal of the insertion sheath 20...”

(See col. 5, lines 64-67 of Leschinski).

One would not have modified Horzewski by applying the teachings of Leschinski to obtain the features of claim 1 and 32, including the internal layer that is discontinuous and non-overlapping. Horzewski focuses on a problem different from Leschinski and is not concerned with allowing only an end to flair open. According to Horzewski, the overlapping layer provides expandability along the length of the tube. There is not a sufficiently presented factual basis establishing that one would add a scored end, as shown in Leschinski, to the configuration of Figure 1B in Horzewski.

Further, one would not substitute the scores 80 of Leschinski for the overlapping layer 14 of Horzewski because the needed expandability along the entire length of the conduit in Horzewski would be lost. This is because the teachings of Leschinski are not applicable to the entire length of the conduit, but rather just the end. If one were to provide the scores 80 of Leschinski along the entire length of element 11 in Horzewski, then the "circumferentially intact" requirement of Horzewski would be lost. Moreover, there is no teaching as to how a plurality of severed and scored strips would perform the needed function of the inner member 14 of Horzewski.

Claim 1 describes, *inter alia*, that the circumference of the inner layer is discontinuous so as to form a discontinuity and is non-overlapping, wherein a portion of the outer layer extends between the discontinuity. Claim 32 contains similar features. Neither Leschinski nor Horzewski teaches or suggests the features of claims 1 and 32, as discussed during the September 15, 2008 interview. Accordingly, claims 1 and 32 are deemed patentable over Horzewski and Leschinski, such that the rejection thereof under 35 U.S.C. § 103(a) should be withdrawn. The rejection of claims 2-5, 13-16 and 37 should likewise be withdrawn at least by virtue of their respective dependencies upon claims 1 and 32.

The features of independent claims 45 and 50 are neither taught nor suggested by Horzewski and Leschinski. Claim 45 recites at least one layer having first and second types of sections varying in a circumferential direction, the circumferential direction lying in a plane perpendicular to a

longitudinal direction of the conduit wherein the elasticity of one of the sections is greater than the elasticity of another one of the sections. Claim 50 contains a similar recitation. For at least the reasons set forth above, one would not combine Horzewski and Leschinski to obtain the claimed features and the references alone or in combination do not teach or suggest the features of claims 45 and 50.

Accordingly, for the multiple reasons set forth above, the combination of Horzewski and Leschinski fails to make obvious the features of independent claims 45 and 50, such that the rejection thereof under 35 U.S.C. § 103(a) should be withdrawn. The rejection of claims 46-49, 51 and 52 should likewise be withdrawn at least by virtue of their respective dependencies upon claims 45 and 50.

Claims 40, 41, 43 and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horzewski. Claims 40, 41, 43 and 44 depend from independent claim 38. As noted above, Horzewski fails to disclose each feature of claim 38. Horzewski also fails to make obvious each feature of claim 38. In particular, there is no factual basis for a skilled artisan to modify Horzewski to provide the claimed first and second types of sections varying in the circumferential direction, the circumferential direction lying in a plane perpendicular to a longitudinal direction of the conduit, wherein the elasticity of one type of section is greater than the elasticity of the other type of section. Horzewski inherently teaches that the respective elements 11 and 14 have a homogenous elasticity in the circumferential direction. Based on the teachings in Horzewski, one would not have gratuitously modified this reference to obtain the unique combination of features found in claim 38, such that this claim is patentable over Horzewski, along with claims 40, 41, 43 and 44 which depend from claim 38.

Claims 7-11<sup>2</sup>, 17, 18, 33-36 and 53-56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horzewski and Leschinski. As noted above, independent claims 1, 32 and 50 are deemed patentable over the combination of Horzewski and Leschinski. Claims 17, 18, 33, 36 and

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<sup>2</sup> Applicant respectfully points out that claims 7-11 are cancelled.

53-55 are patentable over the combination of Horzewski and Leschinski at least by virtue of these claims respectively depending from independent claims 1, 32 and 50.

Claims 26-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horzewski in view of Leschinski and further in view of Querns, et al. (U.S. Patent No. 5,944,691 (hereinafter "Querns")). The grounds of rejection acknowledge that Horzewski and Leschinski fail to disclose how a sheath or catheter is formed. Querns is relied on for a method of co-extrusion to form a sheath. Applicant respectfully submits that the application of Querns fails to make up for the deficient teachings of Horzewski and Leschinski.

In particular, claim 26 describes that the circumference of the inter layer has a discontinuity and is non-overlapping and the circumference of the outer layer is continuous. Claim 26 also recites an operation of providing a portion of the outer layer to extend between the discontinuity. The combination of Horzewski and Leschinski fails to teach or suggest at least this feature, for reasons similar to those set forth above with respect to claims 1 and 32. Further, the application of Querns fails to make up for the deficient teachings of Horzewski and Leschinski, such that claim 26 is patentable over these references. Claims 27-31 are likewise patentable over the applied references at least by virtue of their respective dependencies upon claim 26.

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

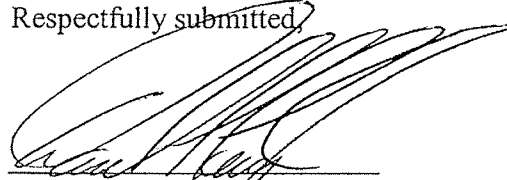
Application No. 10/693,398  
Amendment dated September 29, 2008  
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Docket No.: 0106586.00172US2

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 08-0219, under Order No. 0106586.00172US2 from which the undersigned is authorized to draw.

Dated: September 29, 2008

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David L. Cavanaugh", written over a horizontal line.

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